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| PPLICATION NO. FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|--|----------------------|---------------------|--------------------|--|
| 10/080,053 02/21/2002 | Kenneth Houston | DR-332J | DR-332J 6756 | |
| 7590 11/05/2 | | EXAM | IINER | |
| Iandiorio & Teska | | BEISNER, V | BEISNER, WILLIAM H | |
| 260 Bear Hill Road Waltham, MA 02451-1018 ART UNIT | | PAPER NUMBER | | |

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

| • • | | | | | | |
|---|-------------------------------|------------------------|---|---------------|--|--|
| | Application No. | | Applicant(s) | | | |
| | 10/080,053 | | HOUSTON ET AL. | | | |
| Office Action Summary | Examin r | | Art Unit | | | |
| | William H. Beisner | | 1744 | Ideo as | | |
| Th MAILING DATE of this communication app Period for Reply | pears on the cover s | sheet with the c | orresponaence ad | ur#55 | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. | 36(a). In no event, however | er, may a reply be tim | ely filed | y. | | |
| If the period for reply specified above is less than thirty (30) days, a repleted in NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | will apply and will expire of | pecome ABANDONEI | O (35 U.S.C. § 133). | ommunication. | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | -l | | | | |
| 24) | nis action is non-fin | | recourtion as to th | na marite is | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-14 is/are pending in the application | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-14</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | or election requiren | ient. | | | | |
| Application Papers 9)☐ The specification is objected to by the Examin | er. | | | | | |
| 9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 4) | | ry (PTO-413) Paper N Patent Application (P | | | |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 11 March 2003 has been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 3-4, the claim recites "the sample having a coating for attracting at least one pathogen expected in the sample". This recitation is indefinite because it is not clear how the sample can have a coating. It appears that the claim should actually recited that the "biosensor" has a coating. Clarification and/or corrected is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1 and 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Willner et al.(WO 98/40739).

With respect to claim 1, the reference of Willner et al. discloses a cell biosensor device that includes a vessel for holding a sample to be tested in a medium comprising: a bio-sensor, in the vessel in the culture medium with the sample having a coating for attracting at least one pathogen expected in the sample; and a detection circuit responsive to the bio-sensor for indicating the presence of a pathogen on the bio-sensor (See page 5, line 1 to page 6, line 14; page 15, lines 15-25).

With respect to claims 4, 6-14, the detection circuit operates by driving the biosensor at a predetermined resonant frequency and detecting shifts in the resonant frequency of the biosensor in response to attached pathogens. The detection circuit is continuously driven and instantaneously detects shifts as evidence by the disclosure on page 17, line 28 to page 18, line 4, which states that "frequency changes can be monitored as a function of time".

With respect to claim 5, the detection circuit is external to the sample holding vessel (See page 15, lines 15-25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 9. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al.(WO 98/40739) in view of Karube et al.(EP 0 215 669).

The reference of Willner et al. has been discussed above.

Claims 2 and 3 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

William H. Beisner Primary Examiner Art Unit 1744

WHB